Commodity Management in VCT Programs: A Planning Guide

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Family Health International (FHI) is a nongovernmental organization that operates HIV/AIDS prevention and care programs in more than 40 developing countries. With a staff of more than 400 throughout Africa, Asia, Latin America, the Caribbean, and Europe, FHI's Institute for HIV/AIDS is engaged in numerous research, education, and service delivery activities. FHI's largest program is the Implementing AIDS Prevention and Care (IMPACT) Project, funded by the U.S. Agency for International Development. Through IMPACT, FHI closely collaborates with national ministries of health, community-based organizations, NGOs, and various other agencies. FHI is based in Arlington, Virgina, USA, and can be found on the Web at www.fhi.org.

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
ARV	antiretroviral (drug)
CBO	community-based organization
CDC	U.S. Centers for Disease Control and Prevention
CHL	Central Health Laboratory
EIA	enzyme immunoassay
ELISA	enzyme-linked immunosorbent assay
FHI	Family Health International
GAP	Global AIDS Program
HIV	human immunodeficiency virus
HIV-1	human immunodeficiency virus type 1
HIV-2	human immunodeficiency virus type 2
JICA	Japan International Cooperating Agency
MOH	ministry of health
MSH	Management Sciences for Health
NACP	National AIDS Control Program
NORAD	Norwegian Agency for Development Cooperation
NGO	nongovernmental organization
OI	opportunistic infection
PLHA	people living with HIV/AIDS
PSI	Population Services International
STI	sexually transmitted infection
TRAC	Treatment and Research AIDS Center
TB	tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing
VEN	vital, essential, nonessential (analysis)
WHO	World Health Organization
ZVCTS	Zambia Voluntary Counseling and Testing Services

INTRODUCTION

The goal of this document is to provide practical guidance on commodity management issues related to establishing, managing, and scaling up voluntary counseling and testing (VCT)[1] programs at both national and program levels. This guide is intended to assist a range of audiences—including national program planners and policy makers, donors currently supporting or planning to support VCT service delivery, and VCT service implementers—to systematize their approaches to strengthening VCT services.

Defining Commodities

In the context of health services, commodities include reagents and test kits, laboratory equipment and supplies, condoms, vitamins, and other medical supplies and equipment such as specimen collection tools. For the purposes of VCT, commodities may also include such items as videos and information leaflets. (See the subsequent section called Commodities for VCT—More than HIV Test Kits.) One of the first steps for planners and implementers of VCT services is to decide what items will be included on their VCT commodity list. The focus of this document is the management of commodities for VCT. However, it is recognized that the availability of commodities for related services is critical to the success of comprehensive HIV/AIDS programs. Therefore, issues pertaining to the wider range of HIV/AIDS-related commodities are discussed where appropriate.

Why Commodities Are Critical to the Success of VCT

The Key Elements of Any HIV/AIDS Program Are—

- Prevention of new infections
- Treatment and care of those already infected
- Mitigation of the effects of the disease on individuals and communities

VCT provides entry to an extended range of HIV/AIDS support, care, and prevention activities. However, access to VCT services in many developing countries is limited. The availability of HIV test kits and other commodities for HIV testing, together with a referral system that links to treatment, care, and prevention services where clients can access essential drugs and commodities, is critical to the success of all VCT programs. Although the VCT facility manager's primary concern is to strengthen the commodity management system in order to improve the availability and use of VCT commodities, the system that supplies drugs and commodities to the referral services must also work if the referral service is to function effectively.

[1]For the purpose of this document, VCT is a service that provides pretest counseling, specimen collection, HIV testing, specimen processing, post-test counseling, and follow-up support and care; these services may be provided at one or more sites. This consensual process allows individuals and couples to make an informed choice about being tested for HIV. Individual risk assessment, risk reduction planning, and learning how to cope with test results are integral components of pre- and post-test counseling.

Commodity Availability Affects Demand for HIV Testing

Demand for HIV testing is influenced by an individual's understanding of the importance of the service and by incentives and disincentives for having an HIV test, such as perceived level of confidentiality of the service and options for treatment if the test is positive.

Disincentives for HIV Testing

- Stock-outs of HIV test kits or other essential equipment such as syringes and needles to draw blood may require clients to return another day or go to another clinic.
- Clients are reluctant to spend time and expend resources to travel to a facility where they may be turned away. Many clients who are turned away will not come back.

Incentive for HIV Testing

- Knowing that HIV testing offers entry to a range of prevention, treatment, and care services where drugs and commodities are available and affordable can be a powerful incentive to seek testing.

Commodity Availability Affects the Quality of VCT Services

- Staff attitudes toward clients and service delivery may be negatively affected when the commodities they need to perform their job efficiently and safely are not consistently available, such as when staff must turn clients away repeatedly because of shortages of HIV test kits. Similarly, when gloves and sharps bins to safeguard staff and clients are not available, staff fears regarding infection control are affected, which in turn may exacerbate stigma at the service site.

- Maintaining the enthusiasm and motivation of counselors is difficult when they cannot offer their clients access to preventive services, clinical care, or psychosocial support (either on-site or through direct referral). Service staff must have confidence that they are able to offer their clientele access to the range of services they may need. Access to such services is dependent on the availability of commodities such as drugs for prevention of opportunistic infections (OIs).

- After testing, some clients may not return to obtain their results. The availability of same-day testing through use of rapid test kits has been demonstrated to significantly increase the proportion of clients who receive their test results.

- For many clients, the lack of commodities such as HIV test kits can negatively affect their perception of the quality of the complete VCT service, including counseling. The reputation of the entire service is at stake if commodities are not available.

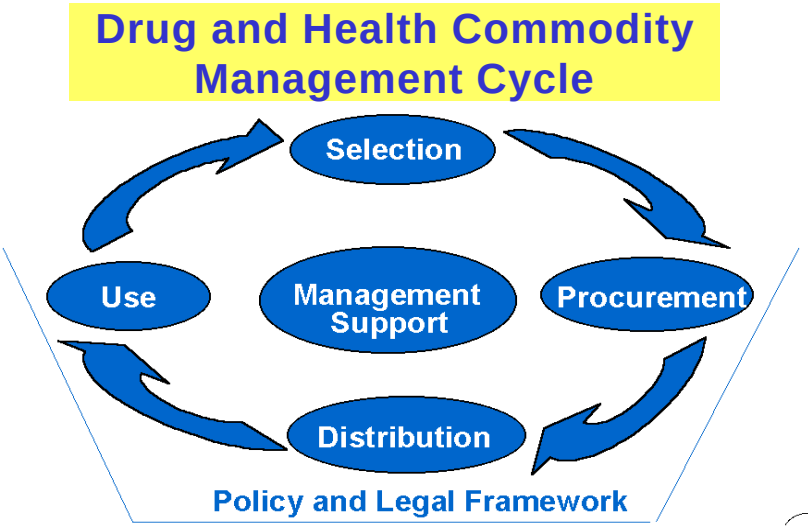
The availability of essential commodities for HIV testing and referral services is important for building and maintaining demand for VCT. Commodity management is the tool to make this happen.

What Is Commodity Management?

Managing drugs, diagnostic test kits, and other health commodities in any setting (public or private sector) and at any level (local, regional, or national) follows a well-recognized system that can be viewed as a cycle of **selection, procurement, distribution, and use** (Figure 1).

At the center of the cycle is **management support.** The functions of management support—financing, information management, staffing, monitoring, and evaluation—hold the cycle together.

The entire cycle rests on a **policy and legal framework** that establishes the mechanisms for each function and supports the commodity management system.



Source: Management Sciences for Health

Figure 1. Drug and Health Commodity Management Cycle

Every piece of the cycle must work well for the next step to occur effectively and efficiently. Problems in any part of the cycle can disrupt the whole commodity management system. For example, if commodity selection is not based on the needs of the population, procurement and distribution of inappropriate products will waste scarce resources, making necessary commodities unavailable. Similarly, it is difficult to encourage rational and appropriate use of drugs and other commodities if shortages occur in first-line products as a result of poor procurement practices, such as inaccurate estimation of quantities needed or lack of transportation to distribute commodities where and when they are needed.

Strengthening national and local commodity management systems is important to ensure that commodities are available and appropriately used.

Commodities for VCT—More than HIV Test Kits

Commodity requirements are largely determined by the service delivery model selected by planners and implementers and by available referral mechanisms. National- and program-level decision makers need to decide which interventions and services to include as part of their VCT program.

This section provides a list of commodities that may be required for a VCT service. It also emphasizes the importance of having a commodity management plan for the VCT program and of taking a systematic approach to address the commodity implications of establishing, managing, and scaling up VCT services.

Commodities needed for VCT may include—

- HIV test kits
- Automated analyzers, such as enzyme-linked immunosorbent assay (ELISA) readers
- Reagents and controls for ELISA testing (if appropriate to the quality assurance strategy)
- Centrifuges
- Refrigerators
- Test-tube racks
- Timers
- Consumables, such as pipettes, pipette tips, and specimen tubes
- Supplies used to collect specimens, such as lancets, needles, syringes, and plasters
- Disposable gloves
- Disinfectants and cleaning supplies

- Sharps disposal bins for needles and lancets as defined under the Universal Precautions strategy
- Waste disposal (biohazard) bags for blood-contaminated materials, such as gauze, swabs, gloves, and testing cards
- Male and female condoms and water-based lubricants
- Tissues
- Safe drinking water and cups
- TV/video equipment and health education videos
- Information leaflets

Commodities needed for VCT services that also offer on-site care or treatment services may include—

- Supplies to diagnose and treat sexually transmitted infections (STIs)
- Contraceptives
- Drugs for palliative and supportive care, such as pain management
- Antiretroviral (ARV) drugs for treatment and prevention of mother-to-child transmission
- Drugs to prevent and/or treat OIs, such as tuberculosis (TB) prophylaxis
- Laboratory equipment and supplies for diagnosing OIs, such as TB
- Laboratory equipment and reagents for monitoring CD4/viral load and side effects of ARVs

STEPS IN MANAGING VCT COMMODITIES

Selection

The first step for national- and program-level planners and implementers is to decide which interventions and services to include in their VCT program. (For more information, refer to the Family Health International [FHI] document entitled *A Guide to Establishing Voluntary Counseling and Testing Services for HIV;* see Additional Resources section for more details.)

National and/or Programmatic Guidelines Required for Effective VCT Services

Standard guidelines for HIV testing must be available or developed at the national level. National and local guidelines should be developed or updated in accordance with international recommendations. The national AIDS coordinating body may need to work with the national essential drugs committee to update the existing national essential drugs list, formulary, or both to reflect the needs of HIV/AIDS programs.

Standard treatment guidelines should also be available for associated prevention, care, and treatment services that require drugs and for other laboratory testing or monitoring. Standard treatment guidelines are disease-orientated guidelines that reflect a consensus on treatments of choice for a range of medical conditions.

The benefits of standard guidelines in relation to commodities include—

- More predictable demand for commodities, allowing for more accurate quantification (estimation of product requirements), thereby reducing shortages and waste
- Expert consensus on the most effective and economical product selection for a specific setting
- Defined basis on which to assess and compare quality of care

At the national level, important questions include—

- Have national guidelines or algorithms for HIV testing been developed or recently updated?
- Do the guidelines include recommendations for performing HIV testing in small-scale settings with limited resources in addition to testing at the central laboratory level?
- Are the guidelines available at the VCT facility level in both the public and private sector?
- Have the guidelines been distributed to donors to ensure that donor-financed procurement of HIV test kits is compatible with national guidelines?

- Have national standard treatment guidelines been developed for prophylaxis and treatment of HIV/AIDS-related diseases?

- Do HIV/AIDS-related drugs need to be included on the national essential drugs list and/or formulary?

The next step at the facility level is to identify the national HIV testing guidelines and/or algorithms and standard treatment guidelines that are relevant for the interventions to be offered.

At the facility level, important questions include—

- If HIV testing will be performed at the facility, what testing guidelines and algorithms will be used?

- Are national testing guidelines and algorithms for HIV available and, if so, are they appropriate for the VCT context and resources?

- For other planned interventions that require drugs and commodities (for example, TB preventive therapy), are national and/or local standard treatment guidelines available?

Evaluating and Selecting HIV Test Kits

Ideally, a national technical advisory group should be established to review and evaluate HIV test kits. The national central laboratory should evaluate the accuracy and operational characteristics of HIV test kits in-country and determine the most appropriate combination and sequence of tests.

The three phases of evaluation take place at the national reference laboratory, at in-country regional laboratories, and at field level. If the laboratory infrastructure at the national level has insufficient capacity to perform the evaluation, the advisory board should—

- Select a test(s) from the United Nations Programme on HIV/AIDS (UNAIDS)/World Health Organization (WHO) list of currently available and WHO-evaluated HIV test kits,[2] ***or***

- Select a testing algorithm based on evaluations by another independent, noncommercial source, preferably in the region.[3] Countries can explore options for regional coordination and collaboration to exchange experiences in developing testing algorithms, particularly for settings with similar epidemiological profiles.

[2]UNAIDS/WHO. 1999. *Operational Characteristics of Commercially Available Assays to Determine Antibodies to HIV-1 and/or HIV-2 in Human Sera*. Report 11. Geneva: UNAIDS/WHO. (An updated document can be obtained by sending an e-mail to unaids@unaids.org or publications@who.int.)
[3]WHO/CDC/UNAIDS. 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation.* n.p.: UNAIDS/WHO.

Eritrea: Strategy Development by National Government Stakeholders

Jan 2001. The Director of the Eritrea Centers for Disease Control Division of the ministry of health (MOH) convened a meeting to discuss the national HIV testing strategy. In attendance were the Director General of Health Services, the Manager of the National AIDS Control Program (NACP), the Director of the Central Health Laboratory (CHL), the Coordinator for Regional Laboratories of the CHL, the Head of the CHL Immunoserology Laboratory, a CHL microbiologist, and the Head of the Central Blood Bank. The meeting focused on routine diagnosis, VCT, certificates for HIV status, mass screening, blood banks, and transfusion.

April 2002. A draft testing strategy was developed and a second meeting called by the Director of the Eritrea Centers for Disease Control Division. In attendance were the NACP Manager, the CHL Director, the Head of the CHL Immunoserology Laboratory, a CHL microbiologist, the Head of the Central Blood Bank, the NACP VCT Coordinator, and the FHI Country Director. The draft document was discussed. Key issues addressed included—

- Quality assurance, especially with peripheral confirmation using rapid tests
- Confidentiality
- Data collection and storage
- Test kits (and which ones to use)
- Source of payment for the tests (and which tests would be free)
- Role of the CHL in training and kit selection and screening, and recommendations for purchase, training, and supervision of testing and quality assurance

April–May 2002. The draft HIV testing strategy was revised on the basis of discussions and circulated to Eritrean and non-Eritrean reviewers. Outside reviewers were from UNAIDS, U.S. Centers for Disease Control and Prevention (CDC), FHI, and an Australian group. The final synthesis of these comments was in progress at the time of this report. The next step is to develop the final version of the strategy and distribute it widely in Eritrea.

Although the CHL is a high-quality public laboratory, a key constraint was the lack of in-country technical expertise to evaluate the available test kits for use in the Eritrean context. Eritrea requires technical assistance for assessment and recommendations for HIV algorithms. Current UNAIDS/WHO information provides a list of what is available on the international market, although limited guidance is available on the suitability of the tests in various circumstances and on the use of the tests in combination for screening, confirming, and tiebreaking.

Factors to Consider When Selecting HIV Test Kits

Enzyme immunoassays (EIAs) versus rapid tests—The testing format selected will depend on the volume of testing and the local capacity to perform testing.

- Rapid tests are recommended in geographically remote areas with little or no laboratory infrastructure and in small hospitals that perform fewer than 100 tests per day.
- Rapid tests are faster than EIAs and generally easier to perform.
- Unlike EIAs, rapid tests offer same-day results, substantially reducing the proportion of clients who do not return for their results.

- EIAs are efficient for batched testing but require sound laboratory structure and trained staff, which may not always be available.

Sensitivity and specificity of the test—The first test should have a higher *sensitivity* (greater than 99 percent), and the second and third tests should have a higher *specificity* (greater than 99 percent). The sensitivity and specificity of the latest generation of rapid tests using immunochromatography are reported to be similar to those of EIAs.

HIV variants and subgroups—Most EIAs and rapid tests detect antibodies to both HIV-1 and HIV-2. However, part of the in-country evaluation should include ensuring that test kits detect the HIV variants and subgroups present in the population tested.

Local capacity—

- It is important to select HIV test kits appropriate for the language, training, and experience of the technical staff who will use them to avoid the expense associated with retraining staff and translating instructions.

- The ability to generate valid and reliable results depends on—

  - Requirements for reagents and equipment
  - Ease of the procedure
  - Number of steps to be performed
  - Ease of interpretation of the test results
  - Inclusion of an internal control to validate the results

- UNAIDS/WHO define four levels of complexity of kits evaluated[4]

  - Level 1: No additional equipment or laboratory equipment required
  - Level 2: Reagent preparation or a multistep process required
  - Level 3: Specific skills such as diluting required
  - Level 4: Equipment and skilled laboratory technicians required

- Rapid tests that use whole blood from a finger prick offer have the advantages of not requiring a centrifuge to prepare plasma or serum and not requiring needles and syringes to draw blood.

Packaging, shelf life, and cost—

- In low-volume settings, kits should be available for use as single tests in pack sizes, which allows the flexibility to adjust the quantity ordered to reflect the number of tests that can be used before the pack expires.

[4]WHO/CDC/UNAIDS. 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation*. n.p.: UNAIDS/WHO.

- The normal shelf life of the product, regular availability from the supplier, and cost per test are also important criteria.

- Consideration should be given to whether the HIV test kits or reagents must be stored in a refrigerator and whether a refrigerator and regular power supply are available in the setting in which the kits will be used.

Factors to Consider in Determining a Testing Strategy and Testing Algorithms

In developing an HIV testing strategy and choosing algorithms, the following factors should be considered—

- Expected HIV prevalence

- Laboratory infrastructure

- Anticipated client flow

- Availability of refrigerators and/or regular electricity supply

- Impact of the protocol on the delivery of health services (for example, same-day testing versus return appointments)

- Cost

- Performance of the test kits (in terms of sensitivity and specificity) in the setting in which they will be used

Testing protocols are designed to maximize both sensitivity and specificity for HIV antibody detection. Several international organizations such as WHO and the U.S. CDC currently provide in-country technical assistance to several countries to help them develop and evaluate national HIV testing guidelines or algorithms that include HIV test kit selection. This section is not intended to be used as a sole reference. Please see the Additional Resources section for more detailed information. The CDC, WHO, and UNAIDS are in the process of preparing a joint publication (expected to be available in 2003) to help countries and program managers select HIV test kits for inclusion in VCT testing guidelines and/or algorithms.

Choosing a Testing Strategy

UNAIDS and WHO recommend three testing strategies to maximize accuracy while minimizing cost. The choice of the most effective strategy depends on the objectives for performing the test—screening, surveillance, or diagnosis—and the prevalence of HIV in the sample population.

Number of tests—The number of tests performed depends on the goal of the testing. Testing algorithms to diagnose HIV infection require at least two (Strategy II) and usually three antibody assays (Strategy III) (see box).

Strategy I

- Requires one test
- For use in diagnostic testing in populations with an HIV prevalence greater than 30 percent among persons with clinical signs or symptoms of HIV infection
- For use in blood screening for all prevalence rates
- For use in surveillance testing populations with an HIV prevalence greater than 10 percent (e.g., unlinked anonymous testing for surveillance among pregnant women at prenatal clinics); no results are provided to the persons tested

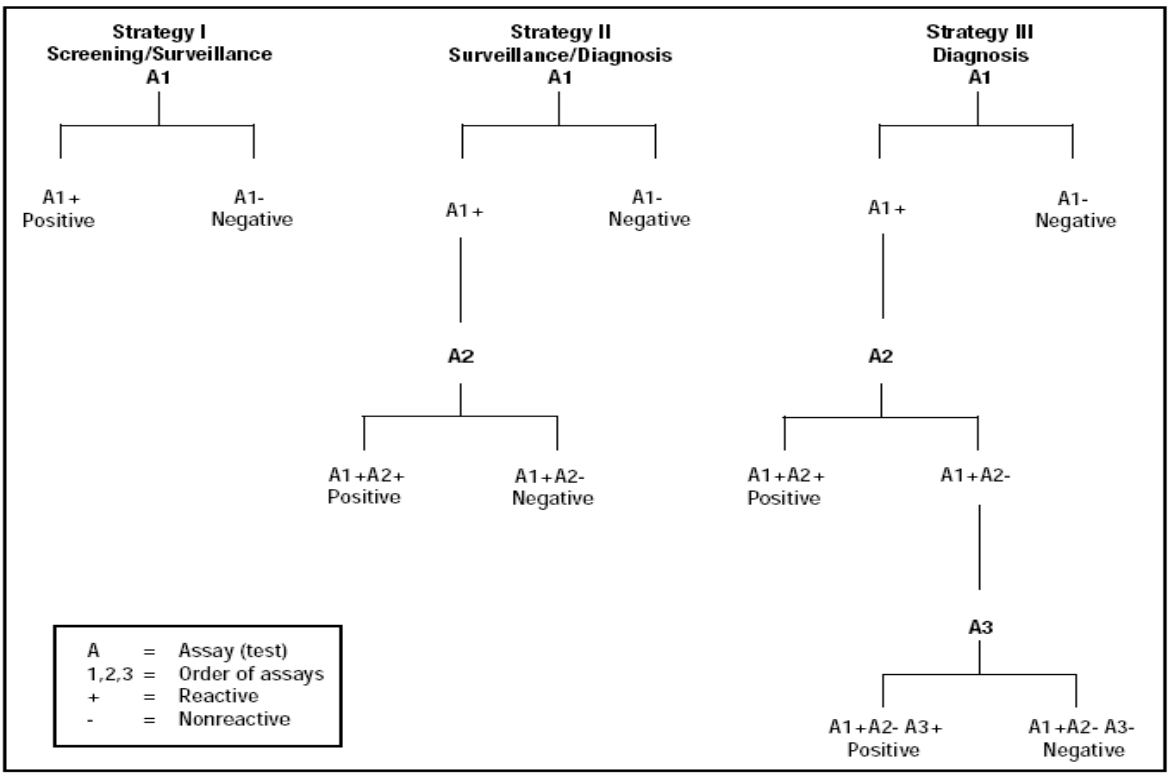
Strategy II

- Requires up to two tests
- For use in diagnostic testing in populations with an HIV prevalence of 30 percent among persons with clinical signs or symptoms of HIV infection or greater than 10 percent among asymptomatic persons
- For use in surveillance testing in populations with an HIV prevalence of 10 percent (e.g., unlinked anonymous testing for surveillance among patients at prenatal clinics or STI clinics); no results are provided to the persons tested

Strategy III

- Requires up to three tests
- For use in diagnostic testing in populations with an HIV prevalence of 10 percent among asymptomatic persons

Source: WHO/CDC/UNAIDS. 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation.* n.p.: UNAIDS/WHO.



Source: WHO/CDC/UNAIDS. 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation.* Geneva: WHO/UNAIDS.

Figure 2. UNAIDS and WHO HIV testing strategies

Order of use—The order of use is determined by the specificity and sensitivity of the tests.

- The sensitivity of a test is the probability of testing positive if infection or disease is truly present. As the sensitivity of a test increases, the proportion of false negatives decreases.

- The specificity of a test is the probability of testing negative if infection or disease is truly absent. As the specificity of a test increases, the proportion of false positives decreases.

- The first test should have a higher sensitivity (greater than 99 percent) and therefore result in fewer false negatives. The second and third tests should have a higher specificity (greater than 99 percent) and therefore result in fewer false positives.

Prevalence—The prevalence of HIV in the population to be tested is a criteria for deciding whether to chose Strategy II or Strategy III. The probability that a test will accurately determine the true infection status of a person being tested varies according to the background prevalence of HIV. In general, the higher the prevalence of HIV in a population, the greater the probability that a person who tests positive is infected. However, as the prevalence of HIV increases, the proportion of false negative results also increases.

Serial versus parallel testing—The advent of rapid test technologies, especially those that use whole blood instead of serum, has also increased the options for testing protocols and procedures to accommodate different service settings and client preferences, namely serial testing and parallel testing. In serial testing, all persons are tested with a rapid HIV test. If the test is positive, a second, different rapid HIV test is performed. Discordant test results are further tested with a third type of rapid HIV test. The tests are performed *in series*. In parallel testing, all persons are tested using two tests simultaneously (*in parallel*). If the tests are discordant—which is estimated to occur less than 1 percent of the time—a third type of rapid test is used as a "tiebreaker." The advantages and constraints of both approaches include patient convenience, patient perceptions of quality, clinic waiting times, source of blood specimen (needle or finger prick), and cost.

Antigen—Methods of antigen production—from viral lysate, synthetic peptide, or recombinant peptide—and the specific combinations of antigens differ with each individual assay. UNAIDS and WHO recommend that the two or three antibody assay tests included in the testing algorithm use different antigens to detect antibodies produced for different parts of the HIV virus.

Testing format—Tests included in the testing algorithm should use different formats or test principles. Current rapid tests are based on four test principles: particle agglutination, immunodot (dipstick), immunofiltration (flow-through device), or immunochromatography (lateral-flow device).

Kenya: A Cross-Sectoral Approach Using Lessons Learned from the Region

A national consultative meeting was convened in September 2001 to discuss VCT in Kenya. The attendees at the meeting asked the Technical Board to help push the agenda for HIV testing forward and develop criteria for the testing algorithm. The following criteria for selection of test kits for use in VCT were developed—

- Results available within 30 minutes
- Does not require refrigeration
- Must be among the WHO-recommended HIV test kits
- Must use whole blood
- Must have been approved for use in Kenya

To determine the particular test kits and testing algorithm, Kenya drew on the U.S. CDC's technical expertise and the experience of the CDC program in Malawi. The decision was made to use a parallel testing algorithm with Determine™ HIV-1/2 and Uni-Gold™ HIV test kits. The plan was to rely on district hospitals to provide the tiebreaker using whatever ELISA technology was available at the time. This approach has been problematic, and donors are working together to identify a suitable third test kit for tiebreaking. Serial testing is also being explored as a means of cost reduction that still provides accurate results to clients.

Rwanda Case Study: A Partnership Approach between Government and Technical Support Agencies

The Treatment and Research AIDS Center (TRAC), formerly the National AIDS Control Program, determined the testing algorithms to be used at VCT sites in Rwanda. The TRAC includes the National Laboratory of Retroviral Infections, which is charged with evaluating rapid tests and developing Rwanda's algorithm. The laboratory technician in charge of these activities at the TRAC lab is hired and seconded by FHI/IMPACT with U.S. CDC funds and is supported with technical assistance by the CDC. Recently, the lab technician evaluated several tests that had not previously been evaluated in Rwanda. The resulting testing algorithm (using a serial strategy) is as follows—

1. First test: Determine™ HIV-1/2
2. Confirmation test: Uni-Gold™ HIV
3. Tiebreaker test: Capillus™ HIV

Initially, the lab selected Genie II HIV-1/HIV-2 as the confirmatory test because of its good performance during the evaluation phase, but experience showed that this test was inappropriate for Rwanda, where refrigeration is extremely limited. In addition, Genie II HIV-1/HIV-2 kits take up a large amount of space, so even where refrigerators exist, there is inadequate space to keep a sufficient supply of tests at a VCT site. With assistance from the CDC, the TRAC selected a different test for confirmation, Uni-Gold™ HIV.

Uganda: A Case Study from a Freestanding VCT Site

In 1999, Uganda's AIDS Information Centre was using the Capillus™ HIV test as a screening test. Confirmatory testing of all positive results was carried out with SeroCard™ HIV with Multispot® HIV-1/HIV-2 being used as the tiebreaker for discordant results. Several problems have been reported with the testing algorithm—

- All the test kits require refrigeration, which is often unavailable at rural hospitals and health centers.
- The number of tests per kit, especially with the tiebreaker (Multispot® HIV-1/HIV-2, 50 tests per kit), meant that waste was a significant problem at sites with a low volume of testing.

Source: Alwano-Edyegu, M. G., and E. Marum. 1999. *Knowledge Is Power: Voluntary HIV Counselling and Testing in Uganda.* Geneva: UNAIDS.

Required Commodities, Drugs, Supplies, and Equipment

The final step in selection is to make a list of all the commodities, drugs, and supplies necessary for VCT. List equipment separately. At the facility level, follow the national or local guidelines where they are available and appropriate. Also consider the following questions—

- What equipment, testing kits, reagents, consumables, and specimen collection supplies are needed to perform HIV tests?
- Does the equipment require unique commercial brands of testing reagents or kit? Does the equipment require specialized preventive maintenance and repair? Are the parts accessible? Is there a service agreement?

- Are refrigerators needed to store test kits, blood samples, or commodities? Is there a regular source of electricity to run refrigerators and equipment?
- What supplies are needed to safeguard the health and safety of the staff performing HIV testing?
- What other commodities and supplies, such as condoms and information leaflets, will be given out by the VCT facility?
- Will the services offered require drugs or diagnostic kits? What drugs and commodities will be needed, and what supplies—such as tablet bottles, labels, and information leaflets—will be needed to dispense of or use them safely? Do staff have the legal authority to dispense medications?

Once lists of all the commodities and equipment have been made, decide if each item is vital, essential, or nonessential. This is called a VEN analysis.

V—*Vital* items are those the provider cannot work without, such as specimen collection equipment for HIV testing.

E—*Essential* items are those the provider would normally always have, such as sharps containers.

N—*Nonessential* items are those that are good to have but can be done without. In HIV testing, an example would be videos.

A VEN analysis should be used to decide how to allocate budget funds if there is not enough to pay for everything; it can also be used to establish priorities for procurement and stock monitoring if storage space or staff time is limited.

Procurement

Quantification—Estimating Quantities of Commodities Needed

The first step in procurement is deciding how much of each commodity to buy. The principles for estimating quantity are the same at the national and facility levels. However, a centralized procurement system is more dependent on an effective management information system to gather accurate and timely usage data from districts and nongovernmental organizations (NGOs).

Some test kit manufacturers and suppliers will help providers quantify their needs (on the basis of the manufacturers' experience with other countries and facilities) and establish delivery schedules. Other VCT program managers may be able to share experiences in creating or expanding VCT services.

A national VCT committee or organization could assist program managers quantify needs or provide training. Coordinating bodies could also work with relevant national bodies, such as the

MOH, to establish management information systems to collect usage data for centralized procurement of VCT commodities.

A program's needs can be quantified in several ways, including—

Consumption or usage method—Uses data on past consumption or quantity used.

- When data are adjusted for stock-outs and projected changes in use, this method gives the most accurate projection of future needs.
- This method is especially useful for large, well-established supply systems.
- To be reliable, the system must have a relatively uninterrupted supply and reliable inventory record keeping (see Distribution section for more details).
- This method assumes products are used rationally; the disadvantage is that it can perpetuate irrational use.

Morbidity method—Uses standard testing and/or treatment guidelines to estimate the need for specific products on the basis of the expected number of client visits to health facilities and the prevalence or incidence of diseases. For VCT, this method uses HIV seroprevalence to estimate the need for HIV test kits (when used for this purpose, it is called the *HIV seroprevalence* method). This method is useful for estimating needs for new programs.

Adjusted consumption or adjusted usage method—Data from other facilities, regions, or countries are adjusted or extrapolated to the specific situation on the basis of population coverage or service level to be provided. This method can be used when other methods are deemed unreliable.

General Principles of Quantification

- Use at least two quantification methods to check your estimates.
- When quantifying needs for a new service or intervention, order extra supplies to "fill the pipeline" (e.g., for filling up shelves in each facility).
- Quantification will need to consider "lead time"—the average time between recognizing that a commodity needs to be ordered to having it available for use. The longer the lead time is, the more safety or buffer stock will be needed to prevent stock-outs between orders.
- Adjust quantification estimates for losses or waste, and take into account the amount of products already in the system.
- No matter which method is used, there is usually a gap between estimated needs and available funds, and decisions will need to be made on how to adjust and reconcile the quantities needed. The VEN analysis will help prioritize what to buy, and the quantification process may help justify an increase in funding or a higher budget when applying to donors.

Quantification for scale-up presents two challenges—

- **Accounting for speed and scale of the planned expansion.** When planning a scale-up, create a monitoring system to ensure that the expansion is proceeding according to plan. Amount of stock ordered may have to be increased or decreased. It is advisable to check and order stock more frequently during expansion when possible, and to adjust quantities ordered to prevent stock-outs or waste.

- **Anticipating changes in the needs of the population being served.** An increase in demand for VCT services can lead to an increase in demand for other services such as STI diagnosis or treatment for OIs.

Examples of how to quantify HIV test kits for VCT services are given in the Appendix.

Where Will Commodities Be Procured?

VCT commodities can be obtained from various sources—

- The product manufacturer
- The WHO HIV Test Kit Bulk Procurement Scheme,[5] which accepts orders from WHO programs, United Nations (UN) agencies, WHO member states, NGOs with official ties to WHO, and other clients such as donor-supported AIDS projects and regulatory bodies
- An international procurement agent or supplier
- Government stores or the central laboratory
- Private pharmacies or wholesalers
- Nonprofit or low-cost international or local suppliers
- Local shops or markets
- Donors
- Companies that coordinate applications for and distribution of donations, such as the Axios Foundation,[6] which coordinates donations of Determine™ HIV-1/2

[5]Information on the WHO HIV Test Kit Bulk Procurement Scheme is available at http://www.who.int/bct/. Follow the links to Key Initiatives/ HIV Diagnostics/ HIV Test Kit Bulk Procurement Scheme.
[6]More information on Axios and the donation programs the foundation manages can be accessed at http://www.axios-group.com/en/.

Considerations when choosing sources of VCT commodities are—

- **Quality of products and service**
  - It is important to use recognized and trusted suppliers who supply good-quality products and operate reliable services.
  - For bulk procurement at the national level, prequalification of suppliers is especially useful to facilitate quality assurance and service.
  - At the facility level, exchange experiences with other program providers to identify reliable sources.
- **Competitive price**
  - Significant savings can be made in tendering for commodities, particularly on the international market and when buying in bulk.
  - Procurement capacity is essential for the system to be successful. Necessary skills include the ability to identify dependable, high-quality suppliers; manage the tender process; negotiate and manage international tenders; and assure product quality.
  - The wide availability and variety of HIV test kits can be a challenge for tendering and can be even more problematic when procurement cycles are short. To prevent frequent product changes and ensure continuity, apply strict criteria when constructing procurement bids.
  - At the facility level, compare prices of different suppliers and consider hidden costs such as transport, delivery times, custom duties, and taxes.
- **Expiration dates and shelf life**
  - Try to obtain stock with as long a shelf life as possible, particularly when procuring drugs for expansion, which may happen more slowly than anticipated.
  - For commodities such as HIV test kits that are manufactured with a short expiration date, consider procuring or scheduling deliveries of smaller quantities more frequently to obtain more recently manufactured stock.
  - Another strategy is to stamp the purchase order with the minimum product shelf life or time before expiration that is acceptable for delivery.
- **Delivery time**
  - Using suppliers with long delivery times can present problems and may require extra storage space and tie up funding in safety stock.

  - Stock-outs or waste can occur when commodities are used erratically or when scaling up occurs faster or slower than planned.

- **Value-added services**

  - Some manufacturers will provide training and additional commodities as part of a competitive package; however, it is important to ensure that none of the factors listed previously are unduly compromised for additional services.

Donations: The Good, the Bad, and the Ugly

Donations of VCT commodities such as HIV test kits can help underfunded programs. But donations can also cause unanticipated problems if they are not carefully controlled and if the donor does not understand the needs of the recipient country or program.

Significant program costs may be incurred in accepting donations, including—

- Fee paid to the national regulatory authority to register the drug or commodity
- Customs duties, taxes, and tariffs
- Storage and distribution costs
- Cost of relabeling in the local language
- Cost of retraining staff to use the donation
- Cost of expensive reagents or equipment needed to use the donation
- Cost of disposing of expired, excess, or unwanted donations, including equipment for which maintenance or spare parts are unavailable

Donated VCT commodities may be incompatible with existing standard testing and/or treatment guidelines and systems and may compromise the quality of the program. WHO guidelines for drug donations (revised in 1999) can assist program managers in making decisions regarding drug and commodity donations.

Many rapid HIV test kits have a short shelf life from the date of production. As a consequence, programs or facilities can be burdened with managing the destruction of outdated test kits if needs are poorly forecast. In addition, lack of continuity of donor support for HIV test kit procurement can affect the quality of VCT services provided.

Communicating needs to donors and letting them know about successes and failures resulting from their donations is important. Consider doing the following—

- Send donors copies of standard testing and/or treatment guidelines and use the VEN analysis and quantification process to let donors know what and how much is needed.

- If donors are unreliable or have erratic delivery dates, suggest they donate nonessential items.

- Specify important requirements such as minimum acceptable shelf life on delivery, language of instructions and labels, and delivery dates when supplies will be needed.

- Suggest donors find other ways to support the VCT program when donations of VCT commodities will cause more harm than good.

Distribution

The principles of stock control, storage management, and delivery to VCT facilities are similar at the national and facility levels.

Storage and Stock Control of VCT Commodities

Important questions for storing VCT commodities include—

- Do any of the commodities have special storage requirements? Is there adequate refrigeration space? Is the electricity supply reliable?

- How much room is needed to store all the commodities between deliveries? Can more storage space be found or more frequent deliveries be scheduled? If scaling up is planned, where will additional commodities be stored?

- Are VCT commodities adequately protected from sunlight and moisture?

- Is the storage area secure to prevent theft and to protect clients and their children from accidental harm from VCT testing commodities, specimen collection equipment, or drugs? Is access to the storage area restricted to accountable staff only?

- Is there a procedure in place for a "cold chain" to maintain and monitor special storage temperatures from delivery of the commodity to storage and use? What system is in place to regularly monitor refrigerator temperature? (Consult colleagues with "cold chain" experience working in vaccine programs for advice.)

Important principles of stock control include—

- **Stock rotation**

  - HIV tests generally have short expiration dates; therefore, it is essential to use the stock with the shortest expiration date first.

  - Drugs for internal use should generally be stored separately from other drugs and commodities.

- **Record keeping**
  - At the national or facility level, it is essential to have a system to track commodities to determine how much and when to order.
  - The system does not necessarily have to be computerized; an accurate, up-to-date manual system is an important first step for computerizing a system.
  - The stock control records or computerized system should also be able to distinguish between what is used and what is wasted and to monitor theft for auditing purposes. An example of a stock card is shown in Figure 3.
  - Use a different card for each product and strength of drug, and record the date every time a supply is received, issued, or expired.
  - Keep a running total of the quantity left and check the stock regularly (e.g., once a month); make a record of any discrepancies on the card.
  - The minimum stock level, reorder level, quantity, and delivery time can also be recorded on the card if these factors are used for procurement.
- **Expired stock**
  - A system should be in place to ensure that expired stock is removed and destroyed safely.
  - It is important to have a national policy to provide guidance on the safe disposal of expired stock and other medical waste. Consider whether assistance needs to be provided at the national level to implement such a policy.

Product Name: Determine HIV-1/2 Card No: /

Strength: Dosage Form: 1 test Issue Unit: 100/kit NSN: 1800978

Size: RECORD OF ORDERS, RECEIPTS & ISSUES Est. Reorder Level: 500

Date	Requisition No.	Quantity Ordered	Voucher No.	To/ From	Quantity Received	Quality Issued	Stock Balance	Unit Price	Remarks
9/4/98							1,000		Stock check /JP
10/4/98	88009	2,000		CMS			1,000		KP
10/4/98				VCT clinic		200	800		JP
11/4/98				Hosp		300	500		Kw. Borrowed
20/4/98			88009	CMS	2,000		2,500	14.5	EXP 3/99 JL
21/4/98				Stock		200	2,300		EXP 12/97 JL
22/4/98							2,100		Stock check/ JL

TOTAL MONTHLY ISSUES

Fiscal Year	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Usage	Expired
FY: 98/99														
FY: /														
FY: /														

Figure 3. Sample stock card

Table 1. How to Use the Stock Card

COLUMN	INFORMATION ENTERED
	1. Entering the Opening Balance
Date	Enter the date stock is checked (e.g., day/month/year)
Stock Balance	Enter the usable (unexpired) quantity in stock according to the Issue Unit (e.g., 1,000 tests)
Remarks	Enter the words "stock check" and the initials of the person who checked the balance
	2. Ordering Stock
Date	Enter the date stock is ordered (e.g., day/month/year)
Requisition No.	Enter the assigned requisition or order number
Quantity Ordered	Enter the quantity ordered according to the Issue Unit (e.g., 2,000 tests)
To/From	Enter the place or institution from which the goods have been ordered
Stock Balance	Stock balance will equal previous balance
Remarks	Enter the initials of the person who placed the order
	3. Tracking Loans
Date	Enter the date stock is borrowed (e.g., day/month/year)
To/From	Enter the location the goods are loaned to or borrowed from
Quantity Received/Issued	Enter the quantity issued or received according to the Issue Unit (e.g., 300 tests)
Stock Balance	Stock balance will equal previous balance minus the quantity loaned or plus the quantity borrowed
Remarks	Enter "Borrowed from" or "Loaned to" and the initials of the person who issued or received the goods
	4. Receiving Stock
Date	Enter the date stock is received (e.g., day/month/year)
Voucher No.	Enter the order number
To/From	Enter the supplier's name
Quantity Issued	Enter the quantity received according to the Issue Unit (e.g., 2,000 tests)
Stock Balance	Stock balance will equal previous balance plus the quantity received
Remarks	Enter the initials of the person who received the goods
	5. Issuing Stock
Date	Enter the date stock is issued (e.g., day/month/year)
To/From	Enter the place or provider the goods are issued to
Quantity Issued	Enter the quantity issued according to the Issue Unit (e.g., 200 tests)
Stock Balance	Stock balance will equal previous balance minus the quantity issued
Remarks	Enter the initials of the person who issued the goods

Delivering and Collecting VCT Commodities and Blood Samples

Distribution presents unique challenges to planners and decision makers at the national level when improving geographical access to VCT is a goal. Success will depend on the effectiveness of the transportation system. The cost of transporting VCT commodities to remote areas or transporting blood samples back to laboratories for testing can be considerable.

Options to improve the distribution system include—

- Strengthen the existing distribution system.
- Use autonomous private or parastatal companies. Autonomous supply agencies are often constituted as parastatals, under either the ministry of health or an independent organization with a board of directors from several government ministries. They operate as nonprofit supply services, and their primary clients are government health services.
- Set up a parallel distribution system.

When planning transportation system improvements, it is essential to thoroughly review the existing system to ensure efficient and rational use of existing resources. Current operating costs should be accurately assessed and compared with the projected cost of alternative systems. Options for strengthening existing distribution systems may include strengthening supervision of staff and rationalizing routes and schedules. Another strategy to improve the existing distribution system is to review the transportation terms for overseas and in-country suppliers and investigate the possibility of requiring direct delivery to lower-level stores.

Using private or parastatal companies can provide cost-effective alternatives for storage and distribution, especially at national or regional levels. Although contracting out distribution to the private sector can create more work—such as assessing the cost of existing systems, preparing tender documents, specifying service requirements, assessing the tenders, and monitoring contractor performance—it also has the potential to improve efficiency.

The temptation for donors to set up parallel distribution systems can be considerable. However, although vertical distribution systems may solve a specific problem at a specific time, they are costly to set up. In addition, systems heavily subsidized by donors are not generally financially sustainable after donor funding discontinues. Before setting up additional parallel systems, donors and donor-funded technical assistance groups should ensure that all existing transportation options are thoroughly reviewed to assess whether using (and strengthening) an existing system would be more sustainable over the long term.

Key considerations at the local level include—

- Rationalizing supply systems to keep transportation and administrative costs down
- Keeping the number of separate suppliers used to a minimum
- Using existing distribution systems where possible and coordinating the collection of commodities from different sources
- Sharing vehicles among programs to reduce costs and improve reliability
- Maintaining storage conditions during transportation for commodities and blood samples that need continual refrigerated storage
- Ensuring that cold storage equipment is included on the list of overall needs

Use of VCT Commodities

Access to commodities alone does not ensure a quality VCT program. Specimens must be correctly labeled and the information correctly recorded to ensure that clients are given correct results. National HIV testing algorithms need to be available at the facility level to guide the selection and use order of rapid HIV tests. Instructions for using HIV test kits must be followed correctly, and staff may need specialized training in reading results. Necessary support services, such as reference laboratories, may need to be developed or strengthened to monitor and evaluate the testing performed in some VCT settings. Information leaflets must be available and given out appropriately.

Some interventions offered as part of VCT services may require drugs or other commodities. Not only must drugs be correctly prescribed and dispensed, but also staff and clients must use drugs and health commodities correctly. Unbiased drug information that staff can understand must be available to enable informed decisions. Tablet containers must be available for medicines, and instructions for clients must be clear and legible. It is critical to provide ongoing staff training on diagnosing, managing, and treating HIV/AIDS-related diseases. Standard treatment guidelines, together with a national essential drugs list, can help standardize and rationalize prescriptions and can be used for in-service training, supervision, and medical audits.

Key considerations at the national level include—

- Have standard testing algorithms and standard treatment guidelines been distributed to VCT facilities in both the public and private sectors?
- Is appropriate and independent information on the use of HIV test kits, drugs, and other commodities available for facilities? Can a list of recommended references and sources be provided?
- Are there donors who could help assemble and disseminate appropriate information?

Questions to ask at the facility level include—

- Are standard testing algorithms and treatment guidelines available and accessible to every staff member who needs them? Do staff have a written, updated protocol to follow?
- Are staff trained to handle specimens and HIV test kits safely and appropriately? Do they need training updates for new tests or procedures?
- If VCT services are going to be scaled up to include new services that require drugs, is information available on using the drugs safely and effectively? Is there information available on side effects, on which drugs cannot be given together, and on when the drugs should not be used? For example, how will staff know which drugs cannot be given to pregnant women?
- Are staff trained and experienced in diagnosing and prescribing appropriate drugs to ensure that the right drug is given in the right dose for the right length of time?

- Is there a system in place for dispensing and labeling medicines to ensure that the right medicines are dispensed, labeled correctly, and given to the right person?

- Can clients follow the drug treatment schedule? Do they understand instructions on taking the drugs and why they are taking them? Can they afford to buy enough drugs to maintain and complete the course of treatment? What will the consequences be if they stop taking the drugs or interrupt treatment?

- What local cultural beliefs and practices exist toward HIV testing and medicines? How can staff work with the community to find ways to support clients or help clients identify ways to support each other to take medicines correctly?

ISSUES TO CONSIDER FOR VCT COMMODITY MANAGEMENT

Policy and Legal Framework

It is important to be familiar with the relevant policies and legislation, including the national HIV testing policy, the national drug policy, drug and commodity legislation and regulation, and legal aspects of commodity procurement. The national HIV testing policy should aim to standardize testing by establishing national algorithms for VCT and other HIV testing contexts within the country. In addition, the policy should outline a procedure for establishing a national external quality control assessment scheme to enroll all laboratories in the public, private not-for-profit, and private for-profit sectors that perform HIV testing.

The national HIV/AIDS committee may need to develop a strategic plan for integrating VCT programs as part of a comprehensive package of services. Policy decisions made at the facility level should include decisions on which services to provide as part of the VCT package, whether to use EIAs or rapid tests, and whether to perform serial or parallel HIV testing.

Planners and program managers should ensure that they are familiar and can comply with legislation that controls the manufacture, supply, storage, prescription, and dispensing of drugs when interventions that require drugs will be offered as part of the VCT package.

Financing

The lack of funding for VCT commodities and consequent lack of HIV testing capacity in VCT facilities in low-resource settings is widely reported.

Options for increasing funding include—

- Present justification for greater government funding
- Introduce or increase user fees (cost sharing)
- Increase or add health insurance coverage for commodities and HIV testing
- Obtain donor assistance

Financial sustainability of VCT is likely to require a combination of financing mechanisms to meet expanding needs. Although user fees can be a useful mechanism to improve financial resources, the fees must be locally appropriate and exemption systems must be established to ensure that user fees do not act as a deterrent to testing (particularly for services targeted to special populations such as the poor, youth, and other vulnerable groups). Service sites in Zimbabwe and Zambia experienced a decline in use of VCT services when user fees were increased (even marginally) while the economy was declining.

Developing a **VCT commodity financing strategy** as part of an overall strategic plan should be high priority at both the national and facility levels. The financing strategy should include efforts to **improve the use of existing funds** by enhancing efficiency within the commodity management system (selection, procurement, distribution, and use). The VEN analysis and quantification exercise should be used to prepare a budget and assist planners and program managers to map out current and potential funding sources and decide how the funding will be used.

In addition, experience with revolving drug funds and broad user-fee programs has shown that programs designed with little attention to management and accounting systems have experienced substantial abuse and little revenue relative to the cost of fee collection.

Donors can be reluctant to finance commodities if there are concerns about sustainability of supply or if there are weaknesses or inefficiencies in the commodity management system. In addition, donors will want to evaluate the impact of the funding given, so it is important to have a functioning management information system to collect data that can be used to evaluate the program. When large amounts of drugs and commodities are being procured and distributed, corruption and theft can become significant. Donors will require good bookkeeping and accounting systems to ensure that resources are managed efficiently. Separating key responsibilities, ensuring proper cash management, providing regular auditing of financial procedures, and making audit reports public can help improve accountability and transparency.

Having a plan ready that comprehensively addresses these issues is important for fund-raising efforts and also assists in responding to requests for proposals for funding when the time from announcement to proposal submission is short. Long-term funding should be assured before certain services are implemented, particularly where clinical outcomes are affected by drug or commodity stock-outs.

Management Information Systems

A commodity management information system collects, reports, and uses information for decision making, including forecasting needs and quantifying procurement. Improving accountability and creating an audit trail to track products that enter or leave the supply system are other important functions.

The system used to collect data should be based on the needs of the users at each level and should build on existing forms, reports, and procedures.

When management information systems need to be strengthened, a low-cost strategy is to start with what already exists. Training and supervising staff to ensure that existing records are filled out correctly and submitted in a timely manner can have a significant effect on improving drug and health commodity supply and use.

Human Resources

The importance of ensuring that national and local VCT programs are adequately staffed—meaning that staff have the required technical and management capacity and are adequately and regularly compensated—cannot be overemphasized. VCT commodity management requires that staff have skills and knowledge not only in clinical and technical areas (e.g., specimen collection, diagnostic criteria, and standard treatment guidelines) but also in supply issues such as quantification and inventory control. Monitoring and evaluating staff skill levels is critical, particularly as the program expands to incorporate new interventions. Some activities can be extremely complex, and it may not always be feasible or desirable to decentralize all commodity management functions, such as procurement and quality assurance, to the facility level.

It is important to determine the skills required for commodity management within the VCT program and to take an inventory of and prioritize staffing and training needs. When defining staff requirements, ensure that staff have adequate time to perform critical tasks such as HIV testing and dispensing of drugs without interruption to minimize the potential for error. VCT program planners and managers can then use the requirements to plan for recruitment or training and also to approach the national coordinating body or donors for assistance in addressing these needs.

Monitoring and Evaluation

Monitoring and evaluation is an integral component of internal and external quality assurance procedures for all facilities where HIV testing is performed. (More information is available in the Additional Resources section.) Certain indicators can be used to monitor the performance of the commodity management system and helping program managers identify and address problems as part of the overall VCT monitoring program. These indicators can be useful in evaluating the impact of an intervention designed specifically to address a commodity management problem and can be essential when reporting back to donors on the impact of commodity donation programs. Part of monitoring and evaluation is having a system in place to record information and track performance over time.

A list of tracer commodities (representative commodities selected for use with performance indicators) is generally used to track the performance of the commodity management system. The first decision is to choose a list of 5 or 10 (depending on the number of items in the inventory) commodities for the tracer list. A sample list could include the screening and tiebreaker HIV test kits used, lancets, gloves, condoms, and information leaflets.

Suggested indicators for monitoring and evaluation include—

- National HIV testing guidelines and/or algorithms for VCT exist and have been updated and/or reviewed in the past three years. (Updated data for inclusion can be provided by the director of the national AIDS coordinating body or the National Reference Laboratory.)

- Percentage of VCT facilities visited that have the most current edition of national HIV testing guidelines and/or algorithms for VCT. Ask the VCT facility program manager to show the most recent copy of guidelines available in the facility.

- Average percentage of a set of unexpired tracer commodities available in VCT facilities. (The product is available if even one unit of unexpired product is in stock in the warehouse or VCT facility.) Ask for the inventory record or stock card for each tracer product and check if there is unexpired stock available for each item.

- Average percentage of time out of stock for a set of tracer commodities in VCT facilities. (Time out of stock is the number of days a product was not present in a warehouse or VCT facility over a recent 12-month period. To be considered in stock, the product cannot be expired. The average percentage time out of stock for a set of products is calculated as the percentage number of days during a 12-month period that each tracer commodity has been out of stock divided by the number of products counted.) Ask for the inventory record or stock card for each tracer drug and check the number of days the product has been out of stock over a recent 12-month period.

- Average percentage of stock records that correspond with physical counts for a set of tracer commodities in VCT facilities. Ask for the stock card showing the current stock level for each key indicator commodity and check the level against stock held on the shelf.

Assuring the Quality of VCT Commodities and HIV Testing

It is important to incorporate quality assurance procedures into VCT commodity supply systems to ensure that each product is safe, effective, and of standard quality. A comprehensive quality assurance program cuts across the four primary components of the commodity management cycle and ensures that—

- HIV test kits, drugs, and other commodities are selected on the basis of safety and efficacy

- Manufacturers meet acceptable performance standards—known as good manufacturing practices—which include criteria for personnel, facilities, equipment, materials, manufacturing operations, quality control, labeling, and packaging

- Sources are recognized as trusted suppliers of good-quality products and operate a reliable service to ensure that commodities meet specified quality standards at the time of delivery

- Quality of commodities is not compromised during storage or transportation

- Recall procedures are implemented to remove defective products

In addition, VCT program managers should develop a comprehensive laboratory quality assurance protocol that includes quality control and assessment of the products, equipment, and HIV testing procedure. Quality control considerations include—

- Quality control procedures should be in place to measure the efficacy of an individual test or reagent when it enters the system and every time it is used. All new test kits and reagents should be evaluated against standards, and known positive and negative controls should be included with each batch tested.

- Internal quality assurance procedures ensure monitoring of the "cold chain"—for example, monitoring the temperature of storage refrigerators for both HIV tests and specimens and checking expiration dates of kits and reagents. Written standard procedures should be in place for training staff on the HIV testing algorithm used, laboratory safety, drawing blood, handling and labeling specimens, testing, and recording and reporting results.

- External quality assurance of the entire HIV testing procedure is generally managed by the National Reference Laboratory, although it can be contracted out to an independent laboratory or provided by one of WHO's regional quality assurance programs. UNAIDS and WHO strongly recommend each country establish a national external quality control assessment scheme that includes all laboratories performing HIV testing in both the public and private sectors.

- External quality assessment should provide evaluation of the efficacy of the testing algorithm used by each facility in addition to assessing laboratory performance. Proficiency testing is a common method used for quality assessment of a laboratory's performance and is generally performed once or twice a year. The National Reference Laboratory should develop a panel of specimens that include known negative, weak, and positive sera that are tested and well characterized on all commercial tests used in the country. This panel is coded and samples are sent out periodically to laboratories for blind testing using their own reagents and procedures. Other external quality assessment procedures include requiring the facility to send 5 to 10 percent of all samples out for external quality assurance.

See the Additional Resources section for further information on quality control and assurance of testing.

VCT Commodity Management for Scaling Up and Linkage to Other Prevention and Care Services

Although the situation varies from country to country, the commodity management systems in many countries are generally able to support the current demand for VCT. However, as national governments and program managers start to scale up VCT services, the systems in place may not be strong enough to support significant expansion. Management information systems and staff data collection skills to track usage and forecast and quantify needs for expansion are generally

lacking. Storage space, particularly refrigerated storage, is insufficient, and distribution systems are limited or nonexistent.

In addition, VCT is now recognized and promoted as an entry point to a range of HIV/AIDS prevention, care, and treatment services. However, the staff of many VCT facilities do not have the necessary skills or time to expand the services they provide, particularly when the services involve procurement and prescribing of drugs. In addition, staff do not have the information or systems in place to refer clients for other services. In many countries, the package of comprehensive HIV/AIDS prevention, care, and treatment services that can and will be offered has not been defined, services that do exist are limited, and essential drugs and commodities are unavailable.

It is essential to begin by clearly defining the goals for scaling up VCT and/or integrating VCT as part of a comprehensive HIV/AIDS package at both the national and facility levels to ensure that the management and supply of commodities appropriately supports those goals. Goals can include—

- Expanding to provide the same services to more people
- Expanding to provide new services to the same people
- Expanding to provide new services to new target populations
- Improving the quality of services currently provided

Once goals have been defined, the next step is to assess the existing VCT commodity system to identify the strengths, gaps, and challenges to expansion. Many of the challenges will be context- or country-specific. It is useful to consider the system as a whole to identify areas for improvement, including major bottlenecks and origins of problems that can appear in several different parts of the system.

Next, identify ways to address the areas that need improvement and target specific areas for the greatest impact. Partnership with and collaboration among national government, NGOs, community-based organizations (CBOs), the private sector, UN agencies, and international donor agencies have been shown to be effective in strengthening the commodity management system for VCT. However, experience has shown that to be successful, a process needs to be established to facilitate coordination, communication, and collaboration; this process should include all stakeholders.

Identifying the key stakeholders and mapping their roles in providing or supporting VCT programs is important. Key questions include—

- Which people or organizations are already involved in providing or supporting national and local VCT programs?

- How are VCT services funded? Who provides funding for what and how much?

- What services do existing VCT programs provide? Who uses the existing VCT services? What is the demand for existing services?

- What commodities do existing VCT programs need? How are they selected? Where do they come from?
- Which organizations are involved in VCT commodity management, including selection, procurement, distribution, and use? Who develops and implements policies and procedures for VCT at the national and local levels? Who is responsible for developing and enforcing legislation and regulation for VCT services?
- Who is responsible for developing and implementing internal and external quality assurance monitoring of VCT programs including HIV testing? How are programs funded, and how effective are they?
- What technical and commodity management training is provided, and who provides it?
- How is commodity management information and data collected, analyzed, used, and shared?

Establishing a process to bring stakeholders to the table to improve coordination can help—

- Identify gaps and duplication
- Allow stakeholders to build on their relative strengths
- Identify successes to build on
- Identify opportunities for streamlining and harmonizing roles and approaches
- Plan for collaborative action to strengthen commodity management systems (It is vital to have clear and agreed upon roles and responsibilities for partners and collaborators.)

The stakeholders and their roles in supporting VCT commodity management will often be context- and country-specific. In many countries, VCT began as a stand-alone service implemented by NGOs and CBOs; in some countries, VCT developed as part of the laboratory services in the public sector. Donors have played a significant role in supporting VCT services and, more recently, in encouraging countries to scale up and integrate VCT as part of a comprehensive package of prevention, care, and treatment. Some of these issues are outlined below.

VCT and the Role of the Private Not-for-Profit Sector

In developing countries, many of the most successful VCT programs are operated by NGOs and CBOs that procure and manage their own supplies. But because staff responsible for these activities often have little or no experience or training in commodity management, they experience difficulties with managing stocks and accurately quantifying requirements, particularly when planning to scale up programs. Stand-alone units are not able to benefit from the economies of scale by buying kits and supplies in bulk, and they lack access to information on suppliers and sources. Some countries have experienced difficulties in setting up management information systems to collect data on HIV testing in NGO facilities, which is vital for

forecasting needs when supplies such as HIV test kits are procured centrally. NGO and CBO staff planning to expand their VCT services may not have or know how to access unbiased information for prescribing and monitoring the side effects of drugs used to prevent OIs or know where to refer clients for other services.

Ensuring that implementing NGOs and CBOs are covered in the mapping process and remain included in the decision-making process to strengthen VCT commodity management systems is key to planning and implementing appropriate interventions to address the specific needs of these implementing organizations.

VCT and the Role of Laboratory Services

HIV testing was initially used to diagnose HIV infection to help medical management and was performed by trained staff in laboratories using ELISA equipment. As a result, in many countries, the national or hospital laboratory service plays a key role in managing the HIV test kits and other supplies for VCT services, in addition to providing quality assurance services for the public and NGO sectors.

However, the commodity management system of the public sector laboratory service has not always been able to meet the needs of the evolving and expanding VCT services. Staff often do not have the skills or a system for gathering and analyzing information to forecast needs for multiunit facilities. Refrigerated storage space is limited, and few laboratories operate a distribution system to deliver supplies to their customers.

As countries and programs consider scaling up VCT services, decision makers will need to decide whether to strengthen the commodity management system of the laboratory services or to integrate VCT commodity supply with the drug/medical supply service.

Role of UN Agencies, Donors, and International Capacity-Building Institutions

Donors play a significant role in supporting the implementation of VCT and helping national governments scale up their VCT services. The U.S. CDC has provided technical assistance to several countries to help them develop and evaluate national HIV testing guidelines or algorithms. WHO evaluates HIV test kits and operates a bulk procurement scheme for selected HIV test kits. More recently, donors have played a role in bringing stakeholders to the table to coordinate roles and facilitate collaboration to strengthen VCT services.

But not all the results of donor support have been positive; there has been a particular problem with HIV test kit procurement. Inconsistent approaches among donors toward HIV test kits has resulted in a wide range of products being available in a single country, as each donor or lender seeks to provide products sourced and produced in its own country for use in the programs it funds. Difficulties have also occurred when donors helping to finance or provide commodities require special accounting practices for their products along with different preconditions, delivery schedules, and procedures.

Where commodity management systems are weak and VCT has been identified as a priority, program managers and particularly donors have established vertical supply systems for VCT

commodities as a short-term fix. Although vertical supply systems may solve a specific problem at a specific time, they are costly to set up, and systems that are heavily subsidized by donors are not generally financially sustainable and can be difficult to administer. In addition, few donors or planners develop a strategy for integrating a vertical supply system into the overall commodity management system in the long term and have not recognized that rationalizing multiple parallel supply systems is ultimately complex, time-consuming, and costly.

Integrating VCT services with already functional service delivery points (in either the public or private sector) is advantageous because the service is easily replicable in the form of a national network of services, increasing VCT availability while providing access to other services. Using existing functional supply systems is likely to make VCT more widely available and more financially sustainable than a stand-alone approach would. Integrating VCT into service delivery points is the approach that Population Services International (PSI), in collaboration with the National AIDS Control Program and the U.S. Agency for International Development (USAID), is using in its New Start Program.

Similarly, planners of VCT pilot programs need to develop a commodity management strategy. Consideration should be given to where supplies will come from and when commodities will be procured or supplied by a donor or a donor-funded agency. The products selected must be compatible with national and/or local guidelines. If the pilot program is eventually to be handed over to the local government or a local organization, the strategy must address where the commodities will come from in the long term and how they will be funded.

Consensus and partnership among international and multilateral capacity-building organizations to facilitate a unified approach to providing technical support to strengthening VCT services in resource-poor countries should be encouraged as much as possible.

CASE STUDY

Zambia VCT Services

Zambia Voluntary Counseling and Testing Services (ZVCTS) was started at the University Teaching Hospital in Lusaka in the late 1990s, mainly with funding from the Norwegian Agency for Development Cooperation (NORAD). The current objectives of ZVCTS are to manage implementation of VCT services, train adequate numbers of VCT staff, review and harmonize HIV testing protocols, streamline information systems, improve tracking of specimens sent for testing, and continue research activities with the virology laboratory (which receives funding from the Japan International Cooperating Agency [JICA]). Other activities include coordination with NGOs and CBOs that introduced VCT in Zambia and that still play a major role in VCT service delivery.

By the end of 2002, 45 new VCT sites are expected to open. In 2001, ZVCTS management and stakeholders identified the following strategies to strengthen VCT services—

- Review and harmonize HIV testing protocols
- Recruit additional laboratory technicians
- Conduct more training
- Strengthen overall capacity of supply management systems

In 2000, six different rapid HIV test kits were used in Zambia due to the lack of harmonization across donors and facilities. Some donated test kits were not included in the national HIV testing protocol or were inappropriate for the technical capacity and local situation. After a thorough literature review and extensive consultation with kit users, stakeholders, and regional laboratory technicians, a testing protocol was adopted nationwide. Initial quantification was performed to estimate commodity and funding needs. In the absence of records, each newly established VCT site estimated needs, which were consolidated centrally by ZVCTS and adjusted based on population, epidemiological data, and projected coverage. The VCT commodity management information system at the facility and central levels still requires strengthening. Accurately quantifying needs remains an ongoing challenge.

Two procurement procedures are used. For local, small-volume ministry of health procurements, ZVCTS quantifies needs and solicits price quotations from wholesalers. Prices are recorded and confirmed with wholesalers before the lowest bid is selected. Prices remain high because transactions are often in small quantities. This procedure is perceived by some as biased toward one or two wholesalers. Procurement of diagnostic kits and medical supplies was, until recently, funded by NORAD and payment was managed by WHO. Kits and supplies were procured directly from manufacturers or their agents. As funds from NORAD decreased, ZVCTS management approached JICA to fill the anticipated gap. Unlike NORAD, JICA purchases products in bulk through a competitive bidding procedure managed by JICA headquarters in Tokyo. As such, the ZVCTS commodity management system had to quantify requirements for one order per year and identify sufficient storage space to hold the entire stock for two years. The microbiology department previously held and managed the stock of test kits and supplies, but it

had insufficient storage space to hold even one year's supply of stock. The decision was made to integrate the VCT supply system into the national supply system and store stock at the Medical Stores Limited. ZVCTS is in charge of distribution, but in most cases VCT facility managers must collect their own supplies because transport is unavailable. Integrating the national supply system, particularly using monthly distribution for the Rural Health Kits, has been proposed to improve distribution of test kits.

There is ongoing need to strengthen and build capacity of the ZVCTS so that it can undertake its emerging and expanding role, which includes responding to requests from VCT sites for technical support and assistance. The service must review its procedures, organizational model, and structure for greater operational efficiency and accountability. The implementation process is in the hands of local authorities; however, sustainability of the program is donor dependent and requires the full political commitment of all stakeholders to ensure long-term viability.

RECOMMENDATIONS

Recommendations for National Governments (National AIDS Control Programs, HIV/AIDS Coordinating Bodies, and Supporting International Technical Agencies)

- Establish an inclusive process to facilitate coordination, communication, and collaboration among key stakeholders and players.

- Develop a VCT commodity financing strategy as part of the overall national VCT and/or HIV/AIDS strategic plan. Ensure that consideration is given to how VCT services will link to or integrate with other facilities and organizations.

- Establish a national technical advisory group to develop and regularly update national HIV/AIDS (including VCT) guidelines and/or algorithms for HIV testing at referral, hospital, clinic-based, and freestanding sites and distribution to counseling and testing facilities, NGO/CBO implementers, and donors.

- Develop standard written procedures to train staff on the HIV testing algorithm, laboratory safety, drawing blood, handling and labeling specimens, testing, and recording and reporting results.

- Send copies of national standard HIV testing guidelines to donors. Communicate needs to donors and let them know what has gone right or wrong with donations.

- Assess needs and develop appropriate training materials and curricula for VCT facility staff.

- Establish a national external quality control assessment scheme that includes all national and peripheral public health laboratories performing HIV testing. Provide guidance for implementers to develop a comprehensive laboratory quality assurance protocol that includes quality control and assessment of the products, equipment, and HIV testing procedures.

- Develop or update national standard treatment guidelines for prophylaxis and treatment of HIV/AIDS-related diseases and referral procedures, and distribute the guidelines to donors, VCT program planners, and implementers. Update the national essential drugs list and/or formulary, if necessary, to include drugs listed on the standard treatment guidelines for HIV/AIDS-related illnesses, HIV test kits, and other VCT-related commodities.

- Provide technical assistance and/or training for quantification of needs and supply management. Establish a management information system to collect usage data for centralized procurement of VCT commodities. Apply strict criteria when constructing procurement bids for tenders to ensure continuity and prevent frequent product changes.

- Develop a policy on the safe disposal of expired stock and other medical waste and consider if assistance is required at the national level to dispose of expired stock.

- Use existing supply and distribution channels where available; if a vertical supply system is established as a short-term fix, develop a strategy for integrating the vertical system into the overall commodity management system.

- Identify, adapt, and distribute appropriate and unbiased information on the use of HIV test kits, drugs, and other commodities.

- Develop country and/or organizational capacity for tendering and bulk procurement of commodities. Assist in identifying dependable, high-quality suppliers. Assist in managing the tender process, negotiating and managing international tenders, and assuring product quality.

- Provide technical assistance to identify the strengths, gaps, and challenges in the existing VCT commodity system, particularly for scaling up or expansion. Work with planners and implementers to address areas for improvement and target specific areas for the greatest impact. Assist organizations in identifying and developing data collection systems to monitor the performance of the commodity supply system.

Recommendations for Donors

- Help countries develop a national long-term strategic plan for scaling up VCT services that includes a commodity financing strategy. Identify appropriate activities to fund or support.

- Fund and facilitate appropriate technical support to strengthen VCT commodity management. Ensure that support or implementation conforms and harmonizes with established in-country policies and procedures.

- Support the development or update of national guidelines or algorithms for HIV testing.

- Ensure that donor-financed HIV test kits and other commodities harmonize with national guidelines and/or standard treatment guidelines.

- Use existing supply and distribution channels when available. If a vertical supply system is established as a short-term fix, develop a strategy for integrating the vertical system into the overall commodity management system for the long term.

- Help countries establish an inclusive process to facilitate coordination, communication, and collaboration between key stakeholders and players.

Recommendations for VCT Implementing Agencies (Government, NGOs, CBOs)

- Develop a long-term strategic plan, including a commodity financing strategy for VCT services, and consider how such services link or integrate with other facilities or organizations. Ensure that the plan is in line with national policies and plans.

- Assess community demand for services to guide what is included in a facility VCT package. Establish linkages with other organizations or service providers who are better placed to provide certain services.

- Develop a directory of care and support services to facilitate referrals within the service area of each facility. Ensure that VCT service providers are familiar with and, when possible, have established working relationships with referral agencies in the directory.

- Ensure that national HIV testing guidelines and/or algorithms and appropriate standard treatment guidelines are available at VCT facilities and available for all staff who are required to adhere to them. Develop facility-based written standard procedures to train staff on the HIV testing algorithm, laboratory safety, drawing blood, handling and labeling specimens, testing, and recording and reporting results.

- Assess training needs of staff, including safe handling of specimens and HIV test kits, and provide updates on new tests or procedures. Monitor and evaluate staff skill levels to incorporate new interventions as programs expand.

- Identify and disseminate to facilities appropriate and independent information on the use of HIV test kits, drugs, and other commodities.

- Ensure that facilities develop a comprehensive laboratory quality assurance protocol that includes quality control and assessment of the products, equipment, and HIV testing procedure.

- Establish a management information system to collect usage data for centralized procurement of VCT commodities. Assess training needs in quantification.

- Identify strategies to use in working with the local community to support clients or help them support each other to take medicines correctly.

- Assess existing VCT commodity systems to identify strengths, gaps, and challenges. Identify strategies to address areas that need improvement and target specific areas for the greatest impact.

- Ensure that VCT facility staff are familiar with relevant policies and legislation including the national HIV testing policy, the national drug policy, drug and commodity legislation and regulation, and legal aspects of commodity procurement. Verify that facilities comply with legislation that controls the supply, storage, prescription, and dispensing of drugs when planning to introduce interventions that require drugs as part of the VCT package.

- Prepare a VEN analysis to decide how to spend budget funds if there is not enough to pay for everything and to establish priorities for procurement if storage space is limited.

- Use recognized and trusted suppliers that provide good-quality products and operate reliable services. Establish a commodities tracking system to monitor how much and when to order. Try to rationalize supply systems to keep transportation and administrative costs down.

ADDITIONAL RESOURCES

For a complete overview of managing drug and health commodity supply systems, including step-by-step approaches on managing pharmaceutical systems effectively:
Management Sciences for Health and World Health Organization. 1997. *Managing Drug Supply.* 2nd ed. West Hartford, CT: Kumarian Press. (Available from Kumarian Press, ISBN #: 1-56549-047-9, http://www.kpbooks.com. Available at a reduced price for developing countries.)

For a summary overview of how to establish VCT services:
Family Health International. 2002. *A Guide to Establishing Voluntary Counseling and Testing Services for HIV.* Arlington, VA: FHI. (Available soon at http://www.fhi.org.)

For information, tools, and other resources to assist NGOs, CBOs, and PLHA (People Living with HIV/AIDS) groups think about issues relating to access to HIV/AIDS-related treatment:
HIV/AIDS Alliance in collaboration with WHO and UNAIDS. June 2002, updated July 19, 2002. *Handbook on Access to HIV/AIDS-Related Treatment.* Available from http://www.aidsmap.com/whatsnew.asp (scroll down under the April 15, 2002, heading for Community Action).

For information on HIV test kits and guidelines on selecting HIV test kits and developing an HIV testing algorithm:
UNAIDS/WHO. 1999. *Operational Characteristics of Commercially Available Assays to Determine Antibodies to HIV-1 and/or HIV-2 in Human Sera.* Report 11. Geneva: UNAIDS/WHO. (An updated document is available by e-mail from unaids@unaids.org or publications@who.int.)

B. M. Branson. 2000. Rapid Tests for HIV Antibody. *AIDS Review* 2:76–83.

UNAIDS/WHO. 1997. Revised Recommendations for the Selection and Use of HIV Antibody Tests. *Weekly Epidemiological Record* 72, no. 12:81–87.

WHO/CDC/UNAIDS. 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation*. n.p.: UNAIDS/WHO.

For information on the WHO HIV Test Kit Bulk Procurement Scheme:
Go to http://www.who.int/bct/. Follow the links to Key Initiatives/ HIV Diagnostics/ HIV Test Kit Bulk Procurement Scheme.

For more information on indicators for assessing commodity management systems:
Management Sciences for Health/Rational Pharmaceutical Management. 1995. *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach*. Arlington, VA: MSH/RPM.

APPENDIX: QUANTIFICATION OF HIV TEST KIT REQUIREMENTS FOR VCT

Terminology

HIV Tests

The first HIV test performed is called the *screening* test, the second the *confirmatory* test, and the third the *tiebreaker*. This terminology is used for both parallel and serial testing, although in parallel testing the screening test and confirmatory test are performed at the same time.

Parallel versus Serial Testing

Quantification of HIV test kit requirements for parallel testing differs from that for serial testing. In parallel testing, two screening tests are performed at the same time on every specimen. In serial testing, only those specimens that have a positive result on the first screening test are tested with the second or confirmatory test. Consequently, the number of confirmatory tests used in parallel testing is much higher than the number used in serial testing. Although parallel testing may offer certain advantages over serial testing, these must be balanced against the significantly higher cost of parallel testing.

Methodology

This section should help facility-level staff calculate the quantity of tests to order. Quantification of test kits for large centralized facilities, or reference laboratories and calculation of requirements to "fill the pipeline" (e.g., to fill shelves at each facility level) are not considered here. The first step in calculating how much to order is to calculate or estimate monthly usage for each type of HIV test kit. Monthly usage can be estimated by either the HIV seroprevalence method or the usage method. New programs will not have existing records, which are needed for the usage method, but can use the adjusted usage method as an alternative. It is advisable to use two methods to check calculations.

Calculation of Monthly Usage (U_m) Using the HIV Seroprevalence Method

This method uses information on population coverage or demand and HIV prevalence to estimate monthly usage. The information needed to use this method is summarized in Table 2.

Table 2. Information Needed to Use the HIV Seroprevalence Method

Information Needed	Why and Where to Get the Information
Number of clients who come for HIV testing	▪ New programs need to estimate the demand for HIV testing. Existing programs that target similar populations should be able to assist in estimating initial demand. ▪ Ongoing programs should be able to estimate demand from existing records, although adjustments may need to be made for anticipated increases or decreases in demand.
HIV prevalence in the population served (%)	▪ Used to calculate requirements of the confirmatory test for serial testing only. ▪ Information on prevalence rates can be obtained from the national AIDS program, prenatal screening, and surveillance programs. National HIV prevalence may not be the same as the prevalence in the population served. ▪ Ongoing programs should keep records to inform calculations of prevalence and monthly usage of confirmatory tests.
Discordant results (%)	▪ Used to calculate requirements of the tiebreaker test. ▪ A discordant result is when the result of the screening test differs from the result of the confirmatory test for the same specimen, requiring a tiebreaker test. ▪ For new programs, consult the national AIDS program, the national testing laboratory, or other programs using the same testing algorithm for estimates. ▪ Ongoing programs should keep records to inform calculations of discordance and monthly usage of tiebreaker tests.
Number of tests used for quality assurance	▪ The CDC Global AIDS Program (GAP) recommends that one positive and one negative control should be run on the day the kit is opened and on every day that the kit is used. Additional controls may be required by the agency supervising quality assurance. ▪ For new programs, consult the national AIDS program, the national testing laboratory, or other programs using the same testing algorithm for estimates. ▪ Ongoing programs should keep records of stock used for quality assurance purposes to guide quantification.
Wastage	▪ No matter how careful and experienced the operator is, a certain number of tests will be wasted because of mishaps and some tests will need to be repeated, when results are indeterminate. Wastage may decrease over time as staff become more experienced or may increase when new staff are trained. Needs for training can be included in wastage, but losses due to expiring stock cannot. ▪ New programs are advised to add 10 percent to requirements to account for wastage. ▪ Wastage should be monitored in ongoing programs to assist in quantification and evaluation of testing expertise.

Calculation of monthly usage (U_m) for serial testing using the HIV seroprevalence method is presented in Table 3.

Table 3. Calculation of Monthly Usage with the HIV Seroprevalence Method

Serial Testing	**Calculation of Monthly Usage (U_m)**
Monthly usage of first (screening) test	= Number of clients estimated who will come for testing per month ***plus*** monthly quality assurance requirements ***plus*** monthly wastage
Monthly usage of second (confirmatory) test	= Number of first (screening) tests needed per month for specimen testing ***multiplied*** by HIV prevalence (%) To the answer ***add*** monthly quality assurance requirements ***plus*** monthly wastage
Monthly usage of third (tiebreaker) test	= Number of second (confirmatory) tests needed per month for specimen testing ***multiplied*** by discordance (%) To the answer ***add*** monthly quality assurance requirements ***plus*** monthly wastage
Parallel Testing	**Calculation of Monthly Usage (U_m)**
Monthly usage of first (screening) test	= Number of clients estimated who will come for testing per month ***plus*** monthly quality assurance requirements ***plus*** monthly wastage
Monthly usage of second (confirmatory) test	= Number of clients estimated who will come for testing per month ***plus*** monthly quality assurance requirements ***plus*** monthly wastage
Monthly usage of third (tiebreaker) test	= Number of clients estimated who will come for testing per month ***multiplied*** by discordance (%) To the answer ***add*** monthly quality assurance requirements ***plus*** monthly wastage

Example 1: Calculation of monthly usage (U_m) using HIV seroprevalence method
A new program estimates 500 clients per month will come for testing from a population where HIV prevalence is estimated to be 30 percent. Requirements for quality assurance testing are estimated to be an additional 10 percent for the screening test, 15 percent for the confirmatory test, and 100 percent for the tiebreaker test. Wastage is estimated to be 10 percent for all three tests. Discordance is estimated to be 2 percent. See Table 4 for calculations.

Table 4. Example of HIV Seroprevalence Method Calculations

Serial Testing	**Monthly Usage (U_m)**
Monthly usage of first (screening) test	= Number of clients estimated that will come for testing per month ***plus*** monthly quality assurance requirements ***plus*** monthly wastage = 500 + (500 × 10%) + (500 × 10%) = 500 + 50 + 50 = **600 tests** (Note that 500 tests are needed for testing specimens and that this figure is used for calculating the monthly usage of the second [confirmatory] test below.)
Monthly usage of second (confirmatory) test	= Number of first (screening) tests needed per month for specimen testing ***multiplied*** by HIV prevalence (%) To the answer ***add*** monthly quality assurance requirements ***plus*** monthly wastage From above, 500 first (screening) tests are needed per month for specimen testing = 500 × 30% = 150 + (150 × 15%) + (150 × 10%) = 150 + 22.5 + 15 = 187.5 Round up to **188 tests** (Note that 150 tests are needed for testing specimens, and this figure is used for calculating the monthly usage of the third [tiebreaker] test below.)
Monthly usage of third (tiebreaker) test	= Number of second (confirmatory) tests needed per month for specimen testing ***multiplied*** by discordance (%) To the answer ***add*** monthly quality assurance requirements ***plus*** monthly wastage From above, 150 second (confirmatory) tests are needed per month for specimen testing = 150 × 2% = 3 + (3 × 100%) + (3 × 10%) = 3 + 3 + .3 = 6.3 Round up to **7 tests**
Parallel Testing	**Monthly Usage (U_m)**
Monthly usage of first (screening) test	= Number of clients estimated who will come for testing per month ***plus*** monthly quality assurance requirements ***plus*** monthly wastage = 500 + (500 × 10%) + (500 × 10%) = 500 + 50 + 50 = **600 tests**
Monthly usage of second (confirmatory) test	= Number of clients estimated who will come for testing per month ***plus*** monthly quality assurance requirements ***plus*** monthly wastage = 500 + (500 × 15%) + (500 × 10%) = 500 + 75 + 50 = **625 tests**
Monthly usage of third (tiebreaker) test	= Number of clients estimated who will come for testing per month ***multiplied*** by discordance (%) To the answer ***add*** monthly quality assurance requirements ***plus*** monthly wastage = 500 × 2% = 10 + (10 × 100%) + (10 × 10%) = 10 + 10 + 1 = **21 tests**

Calculation of Monthly Usage (U_m) with the Usage Method

This method uses inventory stock records to calculate monthly usage (Table 5). The calculation is the same for parallel and serial testing and for all three types of tests.

Table 5. Steps for Calculating Monthly Usage with the Usage Method

Step 1: Calculate number of months the product was in stock during the period being examined	**= *Add*** the number of days the product was out of stock and ***divide*** by 30.5 ***Subtract*** the answer from the number of months during the period being examined
Step 2: Calculate average monthly usage	= Total usage for a given period ***divided*** by the number of months during the period that the product was in stock
Step 3: Make adjustments	Adjust the monthly usage for anticipated increases or decreases in demand and for requirements for quality assurance or wastage

Example 2: Calculation of monthly usage (U_m) with usage method

For an existing program, the following information for the screening test is available from the inventory card. (Note that total usage does not include expired stock removed to be destroyed.)

Fiscal Year	Monthly Usage												Total Usage	Expired
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar		
FY: 01/02	-	-	-	-	-	300	100	0	400	700	700	900	3,100	200

Figure 4. Sample inventory card

Steps to calculate average monthly usage are as follows—

1. Number of months in the period = 7
2. Number of days in the period that product was out of stock = 54
3. Number of months in the period that product was out of stock = 54 divided by 30.5 = 1.8
4. Number of months in the period that product was in stock = 7 minus 1.8 = 5.2
5. Total usage from September to March (7 months) = 3,100
6. Average monthly usage = 3,100 divided by 5.2 = 596

However, in this example, average monthly usage for the past four months is 675 tests and appears to be increasing. Therefore, the program manager decides to use 675 as the average monthly usage to calculate how much to order.

Calculation of Monthly Usage (U_m) with the Adjusted Usage Method

This method uses monthly usage data from other facilities, regions, or countries and is extrapolated for specific situations on the basis of population coverage, prevalence, and requirements for quality assurance and wastage.

Example 3: Calculation of monthly usage (U_m) with the adjusted usage method

A new program is starting in a remote region where prevalence of HIV is estimated from surveillance data to be 20 percent. The program will use the same testing algorithm as a VCT program in another region where prevalence of HIV in clients who use the service is estimated

from records to be 15 percent. Both programs will use serial testing, and levels of discordance are estimated to be similar at 1 percent. It is estimated that demand for the new program will initially be half that of the existing program, which sees 300 clients per month for testing. Requirements for quality assurance will be similar, but wastage is estimated to be double the existing program level of 10 percent. The average monthly usage of the existing program is 360 screening tests, 56 confirmatory tests, and 2 tiebreaker tests per month.

Estimated monthly usage (U_m) of screening test is calculated as follows—

1. Existing program uses 360 tests per month
2. New program is estimated to have half the number of patients = 360 divided by 2 = 180
3. Add 10% for wastage = 180 × 10% = 18 + 180 = 198; round up to 200 tests per month
4. Estimated monthly usage (U_m) = 200 tests per month

Estimated monthly usage (U_m) of confirmatory test is as follows—

1. Existing program uses 56 tests per month
2. New program is estimated to have half the number of patients = 56 divided by 2 = 28
3. Prevalence in the new program is 20% compared to 15% in the new program = 28 × 20% divided by 15% = 37.3
4. Add 10% for wastage = 37.3 × 10% = 3.7 + 37.3 = 41 tests per month
5. Estimated monthly usage (U_m) = 41 tests per month

Estimated monthly usage (U_m) of tiebreaker test is as follows—

1. Existing program uses 2 tests per month
2. New program is estimated to have half the number of patients = 2 divided by 2 = 1
3. As the number of tiebreaker tests used is so small, the adjustments can be rounded up to whole numbers. One extra test can be allowed each month for the higher prevalence and one extra for wastage, so estimated monthly usage (U_m) = 3 tests per month

Calculating How Much to Order

Once monthly usage for each type of HIV test kit has been estimated, it is time to order. The method used to calculate the quantity to order (Table 6) is identical for all three types of HIV test kits regardless of whether parallel or serial testing is used.

Table 6. Calculating How Much to Order

Item	Abbreviation or Calculation	Explanation
Procurement period	PP	The period in months between orders. As the expiration dates of HIV test kits are generally short, kits may need to be ordered more frequently than other supplies. New programs should order more frequently initially—for example, every two or three months—to avoid stock-outs or wastage due to expiring stock.
Lead time	LT	Time between placing an order and the time the product is received and ready to use. For new programs, ask the supplier to submit an estimate of lead time or ask other programs that use the same supplier. Ongoing programs should estimate lead time from existing records.
Stock in inventory	S_I	Stock held in the facility that will not expire in the next procurement period. In a new program, there will be no stock in inventory, so S_I will be zero.
Stock on order	S_O	Stock ordered but not yet received. (Back orders should be included here when there is a system in place to handle them.) In a new program, there will be no stock on order, so S_O will be zero.
Safety stock	$SS = U_m \times$ adjusted LT	Safety stock is stock on hand to protect against stock-outs. At a minimum, safety stock is the average monthly usage (U_m) ***multiplied*** by the lead time (LT). Each program must decide how many months of extra supply to keep. Existing programs should monitor usage and lead time and adjust safety stock to the lowest level compatible with current patterns to keep inventory costs down. Adding one or two months' supply to safety stock is one method of preparing for increased usage.
Maximum stock level (S_{max})	$S_{max} = SS + (U_m \times PP)$	***Multiply*** the average monthly usage (U_m) by the procurement period (PP) and ***add*** the safety stock (SS). Stock levels in a facility should not exceed this level.
Order quantity (in number of tests) (Q_O)	$Q_O = (S_{max}) - (S_I + S_O)$	***Add*** the stock in inventory (S_I) to the stock on order (S_O) and ***subtract this quantity from*** the maximum stock level (S_{max}). This is the quantity of tests that needs to be ordered. ***Divide*** this by the number of tests per kit to obtain the quantity of test kits to order. The number of tests per kit is different for each type or brand of test kit. For a new program, this information can be obtained from the manufacturer or supplier.

Example 4: Calculation of quantity to order

An existing program has calculated that the average monthly usage (U_m) for the screening HIV test is 675. The procurement period (PP) is three months; lead time (LT) is one month; inventory stock (S_I) is 1,900 tests; stock on order (S_O) is 1,000 tests; and because the program is expanding, the program manager decides to add an additional month as safety stock. The tests are packed as 100 tests per kit. Table 7 shows the calculation process for this sample program.

Table 7. Example of Calculations Used in Ordering

Item	Calculation	Calculation for This Example
Average monthly usage	U_m	675 tests
Procurement period	PP	3 months
Lead time	LT	1 month
Stock in inventory	S_I	2,600 tests (but 700 will expire before use at current usage rates, leaving 1,900 tests available for use)
Stock on order	S_O	1,000 tests
Safety stock	SS = U_m × adjusted LT	SS = 675 × (1 month + 1 month) = 675 × 2 SS = 1,350 tests
Maximum stock level (S_{max})	S_{max} = SS + (U_m × PP)	S_{max} = 1,350 + (675 × 3) = 1,350 + 2,025 = 3,375 tests
Order quantity (in number of tests) (Q_O)	Q_O = (S_{max}) – (S_I + S_O)	Q_O = 3,375 – (1,900 + 1,000) = 3,375 – 2,900 = 475 tests
Order quantity (in number of kits) (Q_O)	Quantity in number of tests divided by number of tests per kit	Q_O = 475 divided by 100 = 4.75 kits Round up to **5 kits to order**